

available, what information FDA recommends you submit in support of a request for a fee waiver or reduction, how to submit such a request, and FDA's process for reviewing requests.

FDA is issuing this level 1 final guidance document for immediate implementation consistent with FDA's GGP's regulation (21 CFR 10.115). Prior public participation is not feasible because the guidance concerns statutory requirements that FDA must implement immediately. AGDUFA's user fee provisions are already in effect, and it is essential for the agency to provide guidance on how to request fee waivers and reductions as quickly as possible. If FDA receives comments on this final guidance, it will review the comments and revise the guidance if appropriate.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's GGP's regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the fee waiver provisions of AGDUFA. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork Reduction Act of 1995.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the internet may obtain the guidance at either <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

Dated: May 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-11218 Filed 5-13-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board Subcommittee on Cancer Centers.

Open: June 10, 2009, 6 p.m. to 7:30 p.m.

Agenda: Discussion on Cancer Centers.

Place: Bethesda Hyatt Regency Hotel, One Metro Center, Bethesda, MD 20814.

Contact Person: Dr. Linda K. Weiss, Executive Secretary, NCAB Subcommittee on Cancer Centers, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Suite 700, Bethesda, MD 20892-8345, (301) 496-8531.

Name of Committee: National Cancer Advisory Board.

Open: June 11, 2009, 8 a.m. to 4 p.m.

Agenda: Program reports and presentations; business of the Board.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327. (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Closed: June 11, 2009, 4 p.m. to adjournment.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Open: June 12, 2009, 8:30 a.m. to 12 p.m.

Agenda: Program reports and presentations; business of the Board.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/ncab.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 5, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-11236 Filed 5-13-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Cellular Signaling and Kidney Function.

Date: June 17, 2009.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Atul Sahai, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-2242, sahaia@nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Diabetes, Endocrinology, and Metabolic Disease Fellowships.

Date: June 17-18, 2009.

Time: 6 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Robert Wellner, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 757, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4721, rw175w@nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; DP3 Reviews.

Date: July 15-16, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: D. G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7682, pateldg@nidk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 6, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-11238 Filed 5-13-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, Life Course and Cognitive Impairment in Mexican Americans.

Date: June 25, 2009.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeannette L. Johnson, PhD, Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892. 301-402-7705.

JOHNSONJ9@NIA.NIH.GOV.

Name of Committee: National Institute on Aging Special Emphasis Panel, Proteinopathies in ALS-Dementia.

Date: June 29, 2009.

Time: 10:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: William Cruce, PhD, Scientific Review Officer, National Institute on Aging, Scientific Review Branch, Gateway Building 2C-212, 7201 Wisconsin Ave., Bethesda, MD 20814. 301-402-7704. crucew@nia.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel, US-UK Collaborations in the Biology of Aging.

Date: July 9-10, 2009.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Elaine Lewis, PhD, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC-9205, 7201 Wisconsin Avenue, Bethesda, MD 20892. 301-402-7707. elainelewis@nia.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel, Gene Therapy for AD.

Date: July 9, 2009.

Time: 1:15 p.m. to 4:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person:

Alexander Parsadanian, PhD, Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892. 301-402-7703. PARSADANIANA@NIA.NIH.GOV.

Name of Committee: National Institute on Aging Special Emphasis Panel, Aging Disease.

Date: July 28, 2009.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexander Parsadanian, PhD, Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892. 301-402-7703. PARSADANIANA@NIA.NIH.GOV.

Name of Committee: National Institute on Aging Special Emphasis Panel, Pathways to Health and Illness.

Date: July 28, 2009.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeannette L. Johnson, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892. 301-402-7705. JOHNSONJ9@NIA.NIH.GOV.

Name of Committee: National Institute on Aging Special Emphasis Panel, Mobility Biology and Intervention Study.

Date: August 13, 2009.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact: Jeannette L. Johnson, PhD, Scientific Review Officer, National Institutes